

### SUPPORT FOR THE AMENDMENT

Support for the amendment to claim 6 is found on page 4, line 26 through page 5, line 1 of the specification. No new matter would be added to this application by entry of this amendment.

Upon entry of this amendment, claims 6-13 will remain active in this application.

### REQUEST FOR RECONSIDERATION

The claimed invention is directed to a food product comprising an oil composition and food.

Applicants wish to thank examiners Rae and Kwon for the helpful and courteous discussion held with their U.S. representative on July 26, 2007. At that time, applicants' U.S. representative noted that the claims are directed to an oil composition comprising triglyceride, diglyceride and monoglyceride wherein the diglyceride component contained specified amounts of  $\omega$ -3 unsaturated acyl groups having at least 20 carbon atoms and specific percentages of monoenoic acyl groups. The following is intended to expand the discussion with the examiners.

Diglyceride compositions have gained interest based on a disclosed obesity-preventing effect. In addition,  $\omega$ -3 type unsaturated fatty acids having at least 20 carbon atoms such as docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA), principle components of fish oil triglycerides, have been reported to have beneficial health properties.  $\omega$ -3 Type unsaturated fatty acid have been reported to have very poor oxidation stability (page 2, lines 17-19 of the specification) while diglycerides of  $\omega$ -3 type unsaturated fatty acids have exhibited very high viscosities (page 2, line 27 through page 3, line 5 of the specification). Accordingly, diglyceride containing compositions of  $\omega$ -3 unsaturated fatty acids having good stability and viscosity are sought.

The claimed invention addresses this problem by providing a food product comprising an oil composition and food comprising 0.1 to 59.8 wt. % of triglyceride, about 40 to 99.7 wt. % of diglyceride and 0.1 to 10 wt. % of monoglyceride, wherein the diglyceride component has 15-89.5 wt. % of  $\omega$ -3 unsaturated acyl group having at least 20 carbon atoms with 10-84.5 wt% of monoenoic acyl groups. Applicants have discovered that an oil composition comprising triglyceride, diglyceride and monoglyceride wherein the diglyceride has such a distribution of  $\omega$ -3 unsaturated fatty acids and monoenoic acyl groups provide for an oil composition having good stability and viscosity. Such a composition is nowhere disclosed or suggested in the cited and applied prior art of record.

The rejections of claims 6 under 35 U.S.C. § 102(b) or in the alternative under 35 U.S.C. § 103(a) over Howard et al. (U.S. 3,267,337) are respectfully traversed.

Howard et al. fail to disclose or suggest the claimed food product in which the oil composition comprised triglyceride, diglyceride and monoglyceride wherein the diglyceride is comprised of quantified amounts of  $\omega$ -3 unsaturated acyl groups and monoenoic acyl groups.

Howard et al. describe an edible composition comprising starch, shortening and sugar as well as an alpha-phase crystal-tending emulsifier (column 2, lines 45-50). The alpha-phase crystal-tending emulsified may be a diglyceride of a 1,3-, 1,2- or mixture of 1,3- and 1,2- diglyceride (column 4, lines 13-20). At column 9 is a description of a shortening which may be based on animal, vegetable or marine fats and oils and may bear saturated or unsaturated acyl groups of about 12-22 carbon atoms (lines 5-31). There is no disclosure in the reference of any monoglyceride component. There is no disclosure of unsaturated acyl groups for the diglyceride component. Accordingly, there is no disclosure of an oil composition comprising 0.1 to 59.8 wt. % of triglyceride, about 40 to 99.7 wt. % of diglyceride and 0.1 to 10 wt. % of monoglyceride, wherein the diglyceride component has

15-89.5 wt. % of  $\omega$ -3 unsaturated acyl group having at least 20 carbon atoms with 10-84.5 wt.% of monoenoic acyl groups.

In contrast, the claimed invention is directed to a food product comprising an oil composition and food wherein the oil component comprises 0.1 to 59.8 wt. % of triglyceride, about 40 to 99.7 wt. % of diglyceride and 0.1 to 10 wt. % of monoglyceride, wherein the diglyceride component has 15-89.5 wt. % of  $\omega$ -3 unsaturated acyl group having at least 20 carbon atoms with 10-84.5 wt% of monoenoic acyl groups. Applicants note that claims have been amended to recite the presence of 0.1-59.8 wt. % of triglyceride and 0.1 to 10 wt. % of triglyceride. As the cited reference fails to disclose the claim limitation of a monoglyceride component, the claimed amount of 0.1 to 10 wt. % is clearly neither anticipated nor rendered obvious.

Applicants note that the examiner has asserted that the prior claim limitations of “about 0.1 to 59.8 wt. % of triglyceride” and “0.1 to 10 wt. % of monoglyceride” could be reasonably construed as amounts of zero. While such a proposed construction would be absurd (e.g. unreasonable) as reading out a claim limitation, applicants current claim language makes even more clear the positive presence of a triglyceride and a monoglyceride in the oil phase.

Withdrawal of the rejections based on Howard et al. is respectfully requested.

The rejections of claims 6-13 under 35 U.S.C. 103(a) over Volpenhein U.S. 4,263,216 and Stout et al. U.S. 5,149,851 in view of Brown et al. U.S. 5,288,619, in view of Seiden et al. U.S. 4,680,184, in view of Ainger et al. U.S. 4,214,012, in view of Ciani J. Sci. Food Agric. 1998, 78; 290-0294, in view of Young et al. U.S. 5,085,884 and of claims 6-13 under 35 U.S.C. 103(a) over Wallach U.S. 4,917,951 in view of Brown et al. U.S. 5,288,619, in view of Seiden et al. U.S. 4,680,184, in view of Ainger et al. U.S. 4,214,012, in view of Ciani

*J. Sci. Food Agric.* 1998, 78; 290-0294, in view of Young et al. U.S. 5,085,884 are respectfully traversed.

None of the cited references disclose an oil composition as claimed.

Volpenhein merely describes the preparation of **saturated diglycerides** (column 3, lines 53-55) useful in the manufacture of confectioner's cocoa butter (column 4, lines 43-45). The preparation is conducted with "hardened" triglycerides which are substantially saturated or hydrogenated to be substantially saturated (column 4, lines 30-33). Accordingly, by teaching **substantially saturated** diglycerides, this reference fails to disclose or suggest the claimed invention in which the diglyceride has a content of 15-89.35 wt. % of  $\omega$ -3 unsaturated acyl groups and 10-84.5 wt. % of monoenoic acyl groups. The examiner recognizes this deficiency on page 10 of the official action:

However, Volpenhein does not teach rapeseed oil or fish oils i.e. omega-3 unsaturated fatty acid

Moreover, it would not be obvious to modify the composition of Volpenhein to include unsaturated acyl groups in the diglyceride as substantially saturated acyl groups are selected in order to provide properties to be useful in the preparation of confectioner's hard butter. Volpenhein takes affirmative measures to use a substantially saturated triglyceride starting material such that the substantial saturated nature of the triglyceride makes modification to include unsaturated acyl groups not obvious.

The second primary reference of Stout et al is also flawed in failing to disclose or suggest the claimed unsaturated triglycerides.

Stout et al describes the preparation of **triglycerides** containing unsaturated fatty acid residues, by the reaction of esters of such fatty acids with glycerol (column 2, lines 51-55). The reference describes the desirable nature of  $\omega$ -3 unsaturated acyl groups (column 2, lines 6-16) but in the form of triglyceride compositions, a form which maximizes the number of  $\omega$ -

3 unsaturated acyl groups being delivered. This reference provides no suggestion of an oil composition in which the diglyceride component contains unsaturated fatty acids.

While the official action describes Stout et al as disclosing **triglycerides** as a source of unsaturated fatty acids, the official action fails to identify any teaching in Stoudt et al. relating to **diglyceride compositions**.

The secondary references fail to cure the fundamental flaws of the primary references. Moreover, the examiner has failed to articulate, with any clarity, how the combination of primary and secondary references renders the claimed invention obvious.

The examiner's assertion of obviousness from page 15 is as follows:

Based on the teaching of Brown et al of the incorporation of the specific health promoting fatty acids e.g. omega-3 fatty acids such as eicosapentanoic acids, into triglyceride oils and fats (column 1, lines 26-29), someone of skill in the art at the time the instant invention was made **would have been motivated to combine** the teachings of Volpenhein U.S. 4,263,216 and Stout et al. U.S. 5,149,851 in view of Brown et al. U.S. 5,288,619, in view of Seiden et al. U.S. 4,680,184, in view of Ainger et al. U.S. 4,214,012, in view of Ciani *J. Sci. Food Agric.* 1998, 78; 290-0294, in view of Young et al. U.S. 5,085,884, **to create the instant inventive concept**. (emphasis added)

Such an assertion as to obviousness fails to satisfy the **examiner's burden** to indicate (B) the difference or differences in the claim over the applied reference(s), (C) the proposed modification of the applied reference(s) necessary to arrive at the **claimed** subject matter, and (D) an explanation why one of ordinary skill in the art at the time the invention was made would have been motivate to make the proposed modification. (emphasis added) (M.P.E.P. §706.02(j)). In short the examiner has failed to provide any indication as to the obviousness of the claimed invention but rather merely asserts a motivation to create "the instant inventive concept." Since the instant inventive concept as understood by the examiner is not clear, the examiner has clearly not met his burden of proof of establishing a *prima facie* case of obviousness of the **claimed invention**.

However, the examiner would not be able to establish a *prima facie* case of obviousness as the primary references which relate to a saturated diglyceride composition and an unsaturated triglyceride composition can not be modified to produce the claimed invention of an unsaturated diglyceride containing composition, without destroying the basic teachings of the primary references.

Again, Volpenhein describes **saturated** diglyceride which are necessary to provide a substitute for confectioner's hard butter. It would not be obvious to replace the saturated diglyceride of Volpenhein with unsaturated diglycerides as such a modification would destroy the basic purpose of Volpenhein to provide a composition which behaves as a substitute for confectioner's hard butter.

As to Stout et al., this reference describes the desirable properties of certain unsaturated fatty acid containing composition, such that the unsaturated fatty acids are provided in the form of **triglycerides**, a form which maximizes the delivery of certain unsaturated fatty acids, relative to glycerol. As the reference is concerned with delivery of unsaturated fatty acid, there would be no motivation to reduce the effective concentration of unsaturated fatty acids by replacing unsaturated triglycerides with unsaturated diglycerides.

The deficiencies of the secondary references are addressed as follows:

Brown et al. merely describes the preparation of a **hydrogenated** transesterified stearic acid or stearic acid monoester triglyceride (see Abstract). As a result of hydrogenation unsaturation units as claimed should be destroyed. The reference fails to disclose or suggest the claimed unsaturated acyl groups in a diglyceride.

Even though it is not clear how this reference is being applied in support of the examiner's case of obviousness, Seiden et al. describes an emulsifier for cookies comprising fatty acid mono-diglycerides, fatty acid esters of polyols and fatty acid monoglyceride esters

of polycarboxylic acids (see abstract). There is no disclosure as to  $\omega$ -3 unsaturated acyl groups having at least 20 carbon atoms nor monoenoic acyl groups.

Even though it is not clear how this reference is being applied in support of the examiner's case of obviousness, Ainger et al. is direct to a confectioner's butter substitute (column 3, lines 22-25) which comprises unsaturated fatty acids, but fails to suggest a composition comprising triglyceride, diglycerides and monoglycerides in the amounts claimed.

Even though it is not clear how this reference is being applied in support of the examiner's case of obviousness, Ciani merely describes components of food compositions and fail to disclose or suggest the claimed monoenoic acyl group claim limitation.

Even though it is not clear how this reference is being applied in support of the examiner's case of obviousness, Young et al. describes a nondigestible fat comprising a nondigestible oil and solid polyol fatty acid polyesters having unsaturated ester groups (see abstract). There is no suggestion of the claimed oil composition comprising triglyceride, diglyceride and monoglyceride.

The rejection based on Wallach is even less tenable than the rejections based on Volpenhein and Stout et al.

Wallach is not even related to a food product, but rather directed to lipid vesicles. There is no disclosure of the claimed oil composition comprising triglyceride, diglyceride and monoglyceride. While the reference may provide a disclosure as to polyoxyalkylene fatty acid surfactants, there is no disclosure of glyceride compositions of fatty acids and accordingly the reference is completely irrelevant to the claimed invention.

Further, the examiner has failed to articulate, with any clarity, how the combination of primary and secondary references renders the claimed invention obvious.

The examiner's assertion of obviousness from page 17 is as follows:

Based on the teaching of lipid vesicles for incorporation hydrophilic materials by Wallach, someone of skill in the art at the time the instant invention was made would have been motivated to combine the teachings of Wallach, in view of Stout et al. U.S. 5,149,851 in view of Brown et al. U.S. 5,288,619, in view of Martin et al. (U.S. Patent 3,168,405), in view of Seiden et al. U.S. 4,680,184, in view of Ainger et al. U.S. 4,214,012, in view of Maurizio Ciani, in view of Young et al. U.S. 5,085,884. Thus, **it would have been obvious** to someone of skill in the art at the time the instant invention was made **to create the instant invention** with a reasonable expectation of success in view of Wallach, in view of Stout et al, in view of Brown et al. U.S. 5,288,619, in view of Seiden et al. U.S. 4,680,184, in view of Ainger et al. U.S. 4,214,012, in view of Maurizio Ciani, in view of Young et al. U.S. 5,085,884. (emphasis added)

Such an assertion as to obviousness fails to satisfy **the examiner's burden** to indicate (B) the difference or differences in the claim over the applied reference(s), (C) the proposed modification of the applied reference(s) necessary to arrive at the **claimed** subject matter, and (D) an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification. (emphasis added) (M.P.E.P. §706.02(j)). In short the examiner has failed to provide any indication as to the obviousness of the claimed invention but rather merely a motivation to create "the instant invention." Since the instant invention as understood by the examiner is not clear, the examiner has clearly not met his burden of proof of establishing a *prima facie* case of obviousness of the **claimed invention**.

Accordingly, the combined teachings of the cited references fail to disclose or suggest the claimed oil composition comprising triglyceride, diglyceride and monoglyceride, nor the claim limitations as to  $\omega$ -3 unsaturated acyl groups and monoenoic acyl groups in the diglyceride component. The claimed invention is clearly not rendered obvious by the collection of references and accordingly withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

The objection to the specification as to pages 6, 8, 10, 12, 17, 23, 24 and 28 has not been addressed as the asserted missing/eligible information and/or extraneous markings on

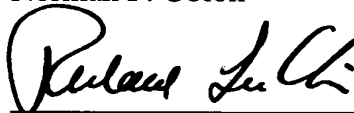


the pages has not obscured the accurate reproduction by the U.S.P.T.O. in the published application 2004/0151824 in paragraphs [0013], [0017], [0019], [0023], [0034], [0048], [0049] and [0062]. As applicants' specification was certainly legible enough for the U.S.P.T.O. to publish applicants' specification, no replacement pages are believed to be necessary.

Applicants submit that this application is now in condition for allowance and early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.  
Norman F. Oblon



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Richard L. Chinn, Ph.D.  
Attorney of Record  
Registration No. 34,305

Customer Number  
**22850**

Tel: (703) 413-3000  
Fax: (703) 413 -2220  
(OSMMN 03/06)

NFO/RLC/law